IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

1FW AF/1765

In re Patent Application of

CANHAM et al.

Serial No. 09/744,152

Filed: February 8, 2001

Title: SILICON MICRO-MACHINED PROJECTION WITH DUCT

Atty Dkt. 124-821
C# M#
TC/A.U.: 1765
Examiner: Duy Vu Nguyen Deo
Date: May 6, 2004

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

☐ **Correspondence Address Indication Form Attached.**

☐ **NOTICE OF APPEAL**
Applicant hereby **appeals** to the Board of Patent Appeals and Interferences from the last decision of the Examiner. ($ 330.00) $

☒ An appeal **BRIEF** is attached in triplicate in the pending appeal of the above-identified application ($ 330.00) $ 330.00

☐ Credit for fees paid in prior appeal without decision on merits -$ ( )

☐ A reply brief is attached in triplicate under Rule 193(b) **(no fee)**

☐ Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) **($110.00/1 month**; $420.00/2 months; **$950.00/3 months**; $1480.00/4 months) $

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Any future submission requiring an extension of time is hereby stated to include a petition for such time extension. The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our **Account No. 14-1140.** A duplicate copy of this sheet is attached.

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By Atty: Paul T. Bowen, Reg. No. 38,009

Signature: _____

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In re Patent Application of

CANHAM et al. Atty. Ref.: 124-821

Serial No. 09/744,152 Group: 1765

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For: SILICON MICRO-MACHINED PROJECTION WITH DUCT

* *

APPEAL BRIEF

On Appeal From Group Art Unit 1765

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In re Patent Application of

CANHAM et al. Atty. Ref.: 124-821

Serial No. 09/744,152 Group: 1765

Filed: January 22, 2001 Examiner: V. Perez Ramos

For: SILICON MICRO-MACHINED PROJECTION WITH DUCT

* *

May 6, 2004

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APPEAL BRIEF

Sir:

I. REAL PARTY IN INTEREST

The real party in interest in the above-identified appeal is QinetiQ Limited by virtue of an Assignment from The Secretary of State for Defence recorded February 20, 2002, at Reel 12831, Frame 459, and an Assignment from the inventors to The Secretary of State for Defence recorded January 22, 2001, at Reel 11512, Frame 407.

II. RELATED APPEALS AND INTERFERENCES

There are believed to be no related appeals or interferences with respect to the present application and appeal.

III. STATUS OF CLAIMS

Claims 1, 3-8, 10-17 and 19-35 stand rejected in the outstanding Final Rejection. The Examiner contends that all claims are either anticipated under 35 USC §102 or obvious under 35 USC §103 in view of the cited prior art.

IV. STATUS OF AMENDMENTS

No further response has been submitted with respect to the Final Official Action in this application.

V. SUMMARY OF THE INVENTION

The present invention relates to the creation of micro-needles, and in particular, a method for making micro-needles, including silicon micro-needles.

It is known to make solid silicon micro-needles as is shown in U.S. Patent 5,457,041 issued to Ginaven et al. where such needles are formed integrally from a silicon substrate. It is also known to provide hollow micro-needles made of metal material as shown in U.S. Patent 5,137,817 issued to Busta et al. Such needles are used for biological testing and others for the provision of small amounts of

material through thin tissue layers into localized cells. Such needles are on the order of microns in length and diameter.

Appellants have invented a novel method of creating such micro-needles, in several embodiments, silicon micro-needles, in that, in one embodiment, instead of building up the needle first, the duct in the silicon is actually first created. Then, through appropriate etching of some of the substrate from around the duct, a micro-needle is formed, with the duct located therein. In another embodiment, the silicon micro-needles is first created and then an appropriate duct therein is formed. In a third embodiment, a first material is provided with a duct, the second material then lines the duct and then the first material is removed leaving a micro-needle of the second material which may or may not be silicon.

Appellants' inventive method comprises two steps (a) **"providing a duct in said silicon substrate"** and, subsequently, (b) **"selectively removing the substrate from around the duct to provide a micro-needle coincident with the duct."** In a further embodiment, the steps comprise "**a. selectively removing the silicon substrate to provide a micro-needle**" and "**b. providing a duct coincident with the micro-needle.**" In a third embodiment, the steps are "**a. providing a duct in said first material**", "**b. lining said duct with a second material**" and "**c. removing said first material**" forming a microneedle with a duct. In all three embodiments the claimed duct is a "**duct passing from said base to said tip.**"

VI. ISSUES

Whether claims 1, 3-8 and 10-16 are anticipated by Ginaven (U.S. Patent 5,457,041).

Whether claims 17 and 19-35 are obvious over Ginaven in view of Busta (U.S. Patent 5,137,817).

VII. GROUPING OF CLAIMS

The rejected claims stand and fall together based upon the allowability of independent claims 1, 8 and 17.

VIII. ARGUMENT

1. Discussion of the References

Ginaven et al (U.S. Patent 5,457,041) teaches the creation of array of solid silicon micro-needles which carry desired genetic material on the tip. Ginaven teaches that silicon micro-machining is capable of creating a solid micro-needle. Such micro-needles are not suitable for the injection or removal of any fluid through a skin layer.

While Ginaven teaches that a solid micro-needle can be created using a number of different methods, he suggests the photolithographic etching fabrication technique as being particularly useful. However, there appears to be no recognition in Ginaven that there would be any desirability of creating a duct in

the needle or that such a duct should pass from the base to the tip of the needle. Instead, it appears that the Ginaven micro-needles, as shown in Figures 4A-4B, have a jagged end or point which serves to retain the biological substance to be transferred and deposited within target cells.

Busta et al (U.S. Patent 5,137,817) teaches the creation of hollow electrodes which are formed of a conductive metal material located on a substrate which have a duct which is capable of passing material into tissues. In fact, the whole point of the Busta reference is that the electrode is conductive in order to apply a voltage differential between adjacent electrodes for the purpose of "electrotransformation of a host cell by electroporation" (Busta, Abstract).

In order to produce the two-material microneedle/substrate arrangement, Busta describes a complicated process (see the passage extending from column 10, line 51 to column 11, line 14) involving many steps and intermediates, including the use of a "proforma". (Polycrystalline silicon region 80 in Busta merely acts as a temporary proforma around which the material forming the electrode is deposited. Silicon region 80 is not present at the start of the process of Busta, and it has been removed by the end of that process. The duct is formed by etching away silicon layer 80 to leave the surrounding jacket formed by conductive layer 86, which had previously been deposited on layer 80.)

There appears to be no disclosure in Busta of making the electrodes out of silicon or, even any non-conductive material. While Busta teaches techniques of

photolithography, they are with respect to the creation of a metal micro-needle and not one of silicon.

2. Discussion of the Rejections

Claims 1, 3-8 and 10-16 stand rejected under 35 USC §102(b) as being anticipated by Ginaven. To the extent it is understood, the Examiner contends that Ginaven discloses the subject matter claimed in appellants' independent claims 1 and 8, i.e., the provision of a silicon micro-needle by the method comprising first providing a duct in the silicon substrate and then the removing of substrate material from around the duct to form a micro-needle (in claim 1) or removing the substrate to form the micro-needle and then providing a duct (in claim 8) in order to provide a silicon micro-needle having a duct passing from the base to the tip.

While appellants have previously queried the Examiner on where the Ginaven reference teaches a duct as recited in appellants' claims and as defines the claimed "silicon micro-needle," the Examiner has relied upon the language of the previous rejection and merely suggests that the region between the tip and the base is a "duct" without identifying any structure in the Ginaven needles which corresponds to appellants' claimed duct. The Examiner appears to have disregarded a specifically recited claim limitation, i.e., the requirement of a "silicon micro-needle" which as is known by those of ordinary skill in the art to

have a "duct passing from said base to said tip." It is noted that this limitation is specifically recited in each of the independent claims 1 and 8.

Claims 17 and 19-35 stand rejected under 35 USC §103 as unpatentable over Ginaven as previously applied and further in view of Busta. The Examiner admits that Ginaven "does not disclose a two-material micro needle as the claimed invention does." However, the Examiner suggests that Ginaven and Busta together teach the subject matter of claims 17 and 19-35, to the extent the rejection is understood. While the Examiner concludes that it would have been obvious to combine the teachings of the two references, he has identified no reason or motivation for combining elements of the Ginaven and Busta references.

3. The Errors in the Final Rejection

There are at least three significant errors in the Final Rejection and they are summarized as follows:

(a) The Examiner errs as a matter of law in failing to give weight to the claim term "duct passing from said base to said tip;"

(b) The Ginaven patent contains no teaching of the claimed duct; and

(c) The Examiner provides no motivation for combining the Ginaven and Busta references.

(a) The Examiner errs as a matter of law in failing to give weight to the claim term "duct passing from said base to said tip;"

Appellants' independent claim 1 defines the claim as a method of providing a "silicon micro-needle," i.e., one having various attributes including a "duct passing from said base to said tip." Thus, appellants' claim is a method of providing a silicon micro-needle which includes the referenced duct.

The claim 1 method requires "providing" a duct in a silicon substrate and subsequently selectively "removing" substrate around the duct to provide the resultant micro-needle. Independent claim 8 similarly recites "selectively removing" the silicon substrate so as to provide a micro-needle and subsequently "providing" a duct coincident within the micro-needle. Independent claim 17 provides a micro-needle in a first material (not necessarily silicon), by "providing" a duct in the first material, "lining" the duct with a second material and "removing" the first material from around the second material, leaving a micro-needle fabricated from the second material attached to the first material and upstanding therefrom. The second material can be any of a number of different materials as related in further dependent claims.

The Examiner has indicated in his Response to Arguments on page 4 of the outstanding Final Rejection that the requirement of a duct "has not been given patentable weight because the recitation occurs in the preamble." The Examiner cites two CCPA cases in support of his proposition, the most current of which is

almost 30 years old. The more recent decisions of the Court of Appeals for the Federal Circuit are binding precedent upon the US PTO and its Examiners. In addition, the Manual of Patent Examining Procedure (MPEP) establishes the basis upon which an Examiner is to evaluate claims. The Examiner's statement and holding is violative of current Federal Circuit precedent, as well as being violative of the MPEP. For example, MPEP Section 2111.02 specifies that "any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation" citing *Corning Glass Works v. Sumitomo Electric USA, Inc.*, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989).

The Examiner suggests that where "the body of the claim does not depend on the preamble for completeness," the preamble limitations can be ignored. However, it is noted in the present instances of claims 1 and 8, the term silicon micro-needle is defined in the preamble of the application, and one of the attributes of the thusly defined silicon micro-needle is the inclusion of "a duct passing from said base to said tip." Moreover, method claim 1 recites "providing a duct in said silicon substrate." Quite clearly, the body of the claim reciting a duct relies upon the definition of a duct set forth in the preamble which characterizes the silicon needle being provided by the claimed method. As set out in the above-noted MPEP section,

> "if the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim."

Pitney Bowes, Inc. v. Hewlett-Packard Co., 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

Finally, the fact that the "duct" is recited in the preamble does not somehow eliminate the recitation of a "duct" in the body of the claims, i.e., "providing a duct." If a prior art reference does not provide a "duct" it is not seen how it can disclose or render obvious the method step of "providing" which is not in the preamble but in the body of the claim.

Thus, in ignoring the requirement of a duct passing from the base to the tip of the silicon micro-needle, the Examiner has erred as a matter of law with respect to a limitation set out in appellants' claims.

(b) The Ginaven patent contains no teaching of the claimed duct

The Examiner has rejected claims 1, 3-8 and 10-16 under 35 USC §102 as being anticipated by Ginaven. The Court of Appeals for the Federal Circuit has noted in the case of *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick*, 221 USPQ 481, 485 (Fed. Cir. 1984) that "[a]nticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim."

Appellants' independent claims 1, 8 and 17 all require the step of "providing a duct." In the first Official Action, the Examiner suggested that there was a "region between the tip and the base (see Fig. 1, the region between tip '28' and the base adjoining substrate '16'; see also col. 7, lines 55-67), which reads on Applicant's 'duc' [sic]." Upon review of the Official Action, appellants responded by Amendment filed May 19, 2003, pointing out that the Examiner appeared to be referencing dotted lines in the figures which relate to the needle diameter and the needle spacing and the needle length, but do not indicate the existence of a duct in the needle.

In response to the Appellants challenge (to point out where there is any disclosure of a duct in the Ginaven) the Examiner has ignored the request and merely copied, virtually verbatim, the language from the first Official Action into the second Official Action.

Even a cursory examination of the Ginaven reference illustrates that there indeed is no duct and the needles are not hollow. There is certainly no duct extending from the tip to the base, and as a result, Ginaven cannot teach the method step of "providing a duct" as recited in independent claims 1, 8 and 17.

As a result, Ginaven clearly fails to anticipate or render obvious any of the independent claims 1, 8 and 17 or any other claims dependent thereon. Should the Examiner believe ducts are shown in the Ginaven reference, he is respectfully requested to point out and identify such ducting in the Examiner's Answer.

(c) The Examiner provides no motivation for combining the Ginaven and Busta references

As noted above, the Ginaven reference teaches solid micro-needles. As previously discussed, the Busta reference teaches conductive metal needles which are formed **on** a substrate and not formed **from** the substrate. Looking at independent claims 1, 8 and 17, the duct is provided in the silicon substrate with respect to claims 1 and 8, and in the "first material" in claim 17. There is no disclosure of this method step in the Busta reference. How or why the Examiner believes the Busta supplies any additional disclosure pertinent to appellants' independent claims is not seen in the Final Rejection.

While the Examiner does refer to the Busta electrodes as having utility in transferring biological substances into target cells, the issue is not the utility of the Busta teaching, but whether the Busta teaching discloses or renders obvious the subject matter of appellants' independent claims. While Busta is cited against claim 17 and claims 19-35, the Examiner suggests that these claims differ from claims 1, 3-8 and 10-16. However, it is noted that claims 27, 33 and 34 depend directly from claim 1, and claims 28-32 and 35 indirectly depend from claim 1. Consequently, the Examiner cannot dismiss the limitations of claim 1 without showing how its limitations are disclosed either in Ginaven or Busta.

The Examiner admits that Ginaven does not disclose a two material micro-needle as the claimed invention does. However, it appears that the Examiner is

suggesting that, because Busta discloses electrodes which could have a final composition similar to the micro-needle disclosed in appellants' claim 17, the process of making that micro-needle is somehow obvious in view of Busta. Thus, in merely comparing the different final needle structures, the Examiner has overlooked the fact that the present invention is directed to a method. The Examiner has not identified how or where Busta teaches the claimed method steps set out in appellants' claim 17, or in any of the other rejected claims, as being disclosed in the Busta reference.

Of course, in addition to the above defects in the Final Rejection, there is no indication or suggestion that one of ordinary skill in the art would combine aspects of the Busta reference with the Ginaven reference. Specifically, the Examiner is reminded that the Court of Appeals for the Federal Circuit has held that "the PTO has the burden under Section 103 to establish a *prima facie* case of obviousness." *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

With respect to the combination of references, the Federal Circuit has also held that "teachings of references can be combined *only* if there is some suggestion or incentive to do so." *Id.* at 1599. Here the Examiner has provided no support for the allegation of it being obvious to combine these references.

The Federal Circuit has also opined that it is "error to find obviousness where references 'diverge from and teach away from the invention at hand'." *Id.* With respect to the alleged motivation for combining these references, the

Examiner has provided no support. In the recent case of *In re Rouffet* , 47 USPQ2d 1453, 1458 (Fed. Cir. 1998), the Court held that "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." Nowhere in either of the cited references does there appear to be any recognition of the problem solved by the claimed invention.

As a result, the Final Rejection simply does not support a rejection of claims 17 and 19-35 as being obvious in view of the Ginaven/Busta combination.

IX. CONCLUSION

In construing appellants' independent claims, the Examiner has ignored the instructions contained in the MPEP and has ignored claim limitations which the Court of Appeals for the Federal Circuit has indicated must be considered. The Examiner misunderstands the teaching of the Ginaven reference and has failed to show how or where it teaches the provision of the claimed duct "passing from said base to said tip". The Examiner has failed to meet the PTO burden of establishing a *prima facie* case of obviousness by indicating how or where there is some motivation for combining the Ginaven and Busta references. Any one of the above errors is sufficient to confirm the impropriety of the Examiner's rejections. All of them together indicate a substantial basis for reversal.

Thus, and in view of the above, the rejections of claims 1, 3-8, 10-17 and 19-35 are clearly in error and reversal thereof by this Honorable Board is respectfully requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

Paul T. Bowen
Reg. No. 38,009

SCS:PTB/kmm/jck
Enclosures
Appendix A - Claims on Appeal

APPENDIX A

Claims on Appeal

1. A method of providing a silicon micro-needle, the micro-needle having a base adjoining a silicon substrate, a tip remote from said base, and a duct passing from said base to said tip, the method comprising:

a. providing a duct in said silicon substrate; and subsequently

b. selectively removing the substrate from around the duct to provide a micro-needle coincident with the duct.

3. A method according to claim 1 wherein a mask is lithographically provided on a substrate of the first material prior to the formation of the duct.

4. A method according to claim 3 wherein the mask is used to provide the duct which is fabricated by any one of the following techniques: plasma enhanced etching, laser ablation, light assisted anodisation, ion beam milling, focused ion beam milling.

5. A method according to claim 1 wherein the micro-needle is bounded by planes of the first material which have a low etch rate.

6. A method according to claim 5 wherein an anisotropic etch is used to selectively remove the first material.

7. A method according to claim 1 wherein the first material is removed by any one of the following methods: focused ion beam milling, etching combined with a domed resist mask.

8. A method of providing a silicon micro-needle, the micro-needle having a base adjoining a silicon substrate, a tip remote from said base, and a duct passing from said base to said tip, the method comprising:

a. selectively removing the silicon substrate to provide a micro-needle; and subsequently

b. providing a duct coincident with the micro-needle.

10. A method according to claim 8 wherein the micro-needle is bounded by planes of the first material which have a low etch rate.

11. A method according to claim 10 wherein an anisotropic etch is used to selectively remove the first material.

12. A method according to claims 8 wherein said micro-needle is formed by any one of the following techniques: focused ion beam milling, etching combined with a domed resist mask.

13. A method according to claim 8 wherein once the micro-needle has been formed a planar surface is provide covering the micro-needle.

14. A method according to claim 13 wherein the duct is provided by lithographic processes performed on the planar surface.

15. A method according to claim 14 wherein once the duct has been provided the planar surface is removed.

16. A method according to claim 1 wherein the method is arranged to provide a micro-needle whose outer walls are inclined to a plane that is perpendicular to the substrate to which the micro-needles are adjacent.

17. A method of providing a micro-needle on the surface of a first material, the micro-needle having a base adjoining the first material, a tip remote from said base, and a duct passing from said base to said tip, the method comprising:

a. providing a duct in said first material,

b. lining said duct with a second material, and

c. removing said first material from around said second material leaving a micro-needle fabricated from said second material attached to said first material and upstanding therefrom.

19. A method according to claim 17 wherein the second material is any one of the following materials: SiO2, a metal, ceramic, a polymer, a semi-conductor.

20. A method according to claim 17 wherein a portion of the second material covering the inside surface of the duct is removed before or whilst the first material is removed from around the second material.

21. A method according to claim 17 wherein the first material is removed by etching.

22. A method according to claim 17 wherein a mask is lithographically provided on a substrate of the first material prior to the formation of the duct.

23. A method according to claim 22 wherein the mask is subsequently u used to control fabrication of the duct.

24. A method according to claim 17 wherein the duct is fabricated using any one of the following processes: plasma based etching, laser ablation, focused ion beam milling, light assisted anodisation of silicon.

25. A method according to claim 17 wherein the second material is provided by any one of the following processes: oxidiation, deposition.

26. A method according to claim 17 wherein the micro-needle is shaped by removing a portion of the second material.

27. A method according to claim 1 in which once the micro-needle has been created the method further includes linking the duct to a reservoir.

28. A method according to claim 27 in which a portion of the first material is removed from a side opposite a side of the first material where the micro-needle has been fabricated.

29. A method according to claim 27 in which the first material is attached to a second piece of material.

30. A method according to claim 29 in which the second piece of material has a channel which connects to the duct and links the duct to a reservoir.

31. A method according to claim 29 in which the first material has a channel which connects to the duct and links the duct to a reservoir.

32. A method according to claim 29 in which the two pieces of material are fabricated from same material.

33. A method according to claim 1 in which the micro-projection is fabricated substantially normal to the surface of the first material.

34. A method according to claim 1 wherein a surface region of the micro-needle is porosified after the needle has been fabricated.

35. A method according to claim 34 wherein the porosification is provided by one of the following techniques: electrochemical anodisation, or immersing the structure is a stain etching solution.